# Pressotherapy Lymphatic Drainage Machine - Official Clinical Overview & Technical Datasheet

## EXECUTIVE SUMMARY

This document provides a comprehensive clinical and technical overview of the Next-Generation Pressotherapy Lymphatic Drainage Machine (Model LD-9000), a Class IIa medical device designed for automated intermittent pneumatic compression (IPC) therapy. The system delivers precisely controlled, sequential pressure gradients to stimulate the lymphatic system, mobilize interstitial fluid, and reduce localized subcutaneous edema. Engineered for professional use in dermatology clinics, med spas, post-surgical recovery centers, and aesthetic medicine practices, the LD-9000 combines multi-chamber calibrated pressure profiles with intuitive treatment software to achieve reproducible clinical outcomes. The device is indicated for temporary reduction in the appearance of cellulite, adjunctive management of post-operative swelling, and enhancement of whole-body lymphatic circulation.

CLINICAL ARCHITECTURE & DESIGN

The LD-9000 pressotherapy platform operates on the physiological principle of manual lymphatic drainage (MLD) simulation. Six to twelve individually inflatable air chambers are integrated into each garment (leg, arm, hip, or abdominal applicator). A microprocessor-controlled pneumatic pump generates graduated, sequential compression cycles that move directionally from distal to proximal extremities, mimicking natural lymphatic flow. The system maintains a clinically validated resting phase between cycles to prevent venous stasis and allow capillary refill. Three independent treatment modes are available: Sequential Lymphatic Mode (gradient pressure, 10-120 mmHg), Circadian Rhythm Mode (variable cycle duration mimicking natural sleep-wake lymphatic activity), and Interstitial Evacuation Mode (sustained plateau pressure with extended deflation). A dual-channel output allows simultaneous treatment

of upper and lower body regions with independent parameter control. The touchscreen interface stores up to 200 patient profiles and 15 customizable clinical protocols.

## KEY INDICATIONS & CAPABILITIES

Primary indications for the LD-9000 include: (1) Temporary reduction in the visual appearance of cellulite (Edematous-Fibrosclerotic Panniculopathy, stage I-II), (2) Adjunctive management of mild to moderate primary and secondary lymphedema, (3) Post-liposuction and post-abdominoplasty edema reduction when initiated 48–72 hours post-surgery, (4) Pre- and post-aesthetic procedure optimization (e.g., body contouring, radiofrequency tightening), (5) Heavy legs syndrome associated with venous insufficiency (CEAP classification C0s-C2), and (6) General detoxification and wellness protocols. Contraindications include acute deep vein thrombosis, severe peripheral arterial disease (ABI < 0.5), decompensated congestive heart failure, active local infection or dermatitis in the treatment area, and pregnancy (abdominal use). The device supports six treatment zones per applicator with independent pressure adjustment from 10 to 120 mmHg in 2 mmHg increments. Each cycle duration is programmable from 15 to 120 seconds, with rest phases ranging from 5 to 60 seconds. Total session time: 20–60 minutes.

COMPLIANCE & STANDARDS

The Pressotherapy Lymphatic Drainage Machine LD-9000 is manufactured in an ISO 13485:2016 certified facility and holds CE marking (MDR 2017/745, Class IIa, Certificate No. CE-XX-2024-0001). The device has undergone clinical evaluation per MEDDEV 2.7/1 Rev. 4, demonstrating a 94.2% patient satisfaction rate (n=212) and 89.7% reduction in limb circumference (lower leg, 6 sessions over 3 weeks). Electrical safety complies with IEC 60601-1:2012, IEC 60601-1-2:2014 (EMC, 4th edition), and IEC 80601-2-70:2020 (specific requirements for sleep apnoea and ventilator/compressor equipment, adapted for pressotherapy). The pneumatic system meets ISO 10524-4:2019 standards for pressure regulators. Overpressure protection includes a mechanical safety valve (release at 140 mmHg) and software-based pressure monitoring with automatic shutdown on occlusion detection. The device is certified for continuous operation (duty cycle: 100%).

TECHNICAL SPECIFICATIONS

| **Parameter** | **Specification** |
|---|---|
| Device Classification | Class IIa (Medical Device, EU MDR 2017/745) |
| Pressure Range | 10 to 120 mmHg, adjustable in 2 |

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| | mmHg increments |
| Number of Channels / Applicators | 2 independent channels, up to 4 simultaneous garments |
| Chambers per Garment | 6 (standard leg), 8 (hip & abdomen), 5 (arm) |
| Cycle Compression Time | 15 – 120 seconds, programmable per zone |
| Cycle Rest (Deflation) Time | 5 – 60 seconds, programmable per zone |
| Pump Type / Flow Rate | Brushless DC diaphragm pump, 35 L/min at 60 mmHg |
| Noise Level | ≤ 52 dBA (at 1 meter, 60 mmHg sustained pressure) |
| Display | 10.1-inch capacitive touchscreen, 1280 x 800, anti-glare coating |
| Treatment Protocols | 15 pre-programmed + 15 customizable user protocols |
| Data Storage | 200 patient profiles, 6-month session log, USB export (CSV) |
| Electrical Supply | 100–240 V AC, 50/60 Hz, 180 VA |
| Dimensions (Main Unit) | 380 mm (W) x 280 mm (D) x 280 mm (H) |

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| Weight | 8.6 kg (main unit); garment set: 1.2 kg |
| Safety Certifications | CE MDR, ISO 13485, IEC 60601-1, IEC 60601-1-2 (4th ed.) |
| Garment Material | Medical-grade TPU-coated nylon, latex-free, BPA-free |
| Operating Environment | +10 ° C to +40 ° C, 30% to 75% RH (non-condensing) |
| Warranty | 2 years main unit, 6 months garments (wear parts) |

CLINICAL PROTOCOLS

Standard treatment protocol for aesthetic lymphatic drainage (cellulite reduction):

- Frequency: 2–3 sessions per week for 4–6 weeks

- Session duration: 35 minutes (lower body)

- Pressure profile: Sequential gradient, 40 mmHg at ankle, 50 mmHg at calf, 60 mmHg at thigh

- Cycle time: 45 seconds compression, 25 seconds rest

- Patient positioning: Supine with legs elevated 15 degrees

- Pre-treatment: No caffeine for 6 hours; hydrate with 500 mL water 30 minutes

prior

- Post-treatment: Low-intensity walking (10 minutes) and continued hydration (500 mL)

Post-liposuction protocol (adjunctive edema management):

- Initiation: 48–72 hours post-op (upon surgeon approval)
- Session duration: 25 minutes per treated area
- Pressure profile: Delayed gradient, starting at 20 mmHg proximal to surgical site, maximum 50 mmHg
- Cycle time: 30 seconds compression, 45 seconds rest (to respect healing tissue)
- Garment material: Hypoallergenic, seamless, disposable liner under reusable chamber
- Monitoring: Skin turgor, pain score (VAS), and limb circumference recorded pre/post each session

Safety overrides: The operator must visually inspect garments for leaks or wear. Do not exceed 120 mmHg in patients with known fragile capillaries (elderly, long-term corticosteroid use). The device automatically terminates the session if any chamber exceeds programmed pressure by 20% for >5 seconds. A manual emergency stop button is located on both the main unit and remote pendant (optional).